

Appln. No. 10/583,370  
Amd. dated August 1, 2008  
Reply to Office Action of May 1, 2008

**REMARKS**

The Office Action and the cited and applied reference have been carefully reviewed. No claim is allowed. Claims 19, 21-23, 25, 28, 31-41, 43-46, 48, 50, 53-55, 57 and 58 presently appear in this application, with claims 33-39 being withdrawn from consideration by the examiner, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Regarding applicants' traversal of the restriction requirement, the examiner indicates that, contrary to applicants' arguments, applicants are arguing limitations not present in the claims and therefore the method described in the Kovalovich reference meets the limitations of Group I. The specific dose range recited in dependent claims 24 and 49 are now incorporated into independent claims 19, 40, 41 and 55. Accordingly, the present claims do indeed define a special technical contribution over Kovalovich and the prior art. Reconsideration and withdrawal of the restriction requirement are therefore respectfully requested.

Claims 19-25, 28, 31-32, 40-50 and 53-58 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while enabling for a method of inducing proliferation of hepatocytes in CC14 induced

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chemical cirrhosis, does not reasonably provide enablement for a method for treating liver injury as recited in claim 1. This rejection is respectfully traversed.

Applicants have now amended the claims to be directed to "treating liver cirrhosis". As defined by DORLAND's ILLUSTRATED MEDICAL DICTIONARY, 30<sup>th</sup> edition, Saunders, 2000, a copy of the relevant definition being attached hereto, "cirrhosis" is liver disease characterized by diffuse interlacing bands of fibrous tissue (i.e., scar tissue) dividing the hepatic parenchyma into micronodular or macronodular areas. Also attached is a definition from Wikipedia. It can be seen from this definition that cirrhosis is simply scar tissue and nodules that are the result of injury or other liver tissue damage. It does not matter what causes the injury for one to get cirrhosis; cirrhosis is cirrhosis no matter what causes the damage.

The present specification discloses at page 3, lines 8-12, that Kokudo et al., *J. Surg. Res.* 52:648-655 (1992) established that the carbon tetrachloride/phenobarbital model is a valid model for impaired liver regeneration and liver cirrhosis, where micronodular cirrhosis was achieved by simultaneous administration of carbon tetrachloride and phenobarbital. A copy of the abstract from the Kokudo et al. (1992) publication is attached hereto.

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Also attached are copies of the Ortiz et al., *J. Am. Soc. Nephrol.* 7:2694-2699 (1996) reference and abstracts from three references, which are representative of the knowledge in the art that the carbon tetrachloride and phenobarbital model is recognized and understood to be a model for cirrhosis in general.

It is further pointed out that applicants did not discover the effect of IL-6 on liver injury; rather, this was reported by the Kovalovich in larger doses for various liver injuries based on the carbon tetrachloride/Phenobarbital model.

Accordingly, the presently amended claims are indeed enabled for treating liver cirrhosis with the recited low dose of IL-6.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 19-25, 28, 31-32, 40-50 and 53-58 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is believed to be obviated by the amendment to the claims.

Applicants do not understand the rejection of claims 19, 40 and 41 for failure to recite method steps, as these claims all recite the active step of administering to a patient in need thereof.

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With regard to the recitation of "an expression vector" as non-elected subject matter, as indicated above, reconsideration of the restriction requirement is being respectfully requested in view of the special technical feature that provides a contribution over Kovalovich and the prior art.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 19-22, 28, 31-32, 40-42, 43, 45, 50, 53-54 and 55-58 have been rejected under 35 U.S.C. §102(b) as being anticipated by Kovalovich et al. (2001). This rejection is obviated by the amendment to claims 19, 40, 41 and 55 to incorporate the dose range recited in claims 24 and 49.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 19, 28, 31-32, 40-41, 43, 48 and 50 have been rejected under 35 U.S.C. §102(b) as being anticipated by Selzner et al. (1999). This rejection is also obviated by the amendment to claims 19, 40 and 41 to incorporate the dose range recited in claims 24 and 49.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

New claims 59-62 are supported in the specification at page 10, lines 7-9.

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In view of the above, the claims comply with 35 U.S.C.  
§112 and define patentable subject matter warranting their  
allowance. Favorable consideration and early allowance are  
earnestly urged.

Respectfully submitted,

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